

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PUREWICK CORPORATION,

Plaintiff/Counterclaim Defendant,

v.

SAGE PRODUCTS, LLC,

Defendant/Counterclaim Plaintiff.

C.A. No. 19-1508-MN

**SAGE'S OPENING BRIEF IN SUPPORT OF ITS MOTIONS FOR RENEWED
JUDGMENT AS A MATTER OF LAW AND NEW TRIAL ON INFRINGEMENT,
INVALIDITY, WILLFULNESS, AND DAMAGES AND REMITTITUR AND
CONDITIONAL MOTION TO AMEND THE JUDGMENT**

Dated: May 5, 2022

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TABLE OF CONTENTS

TABLE OF AUTHORITIES	III
NATURE AND STAGE OF PROCEEDINGS	1
SUMMARY OF THE ARGUMENT AND ARGUMENT	2
I. LEGAL STANDARDS FOR JMOL AND NEW TRIAL.....	3
II. JMOL AND A NEW TRIAL ON INFRINGEMENT IS WARRANTED	4
A. JMOL And A New Trial On The 376 And 989 Patents Should Be Granted.....	4
1. There Was No Evidence That <u>Sage</u> Practiced The 989 Patent	4
2. There Was No Evidence of Direct Infringement Of The 989 Patent By Any Entity (Much Less After August 2019).....	4
3. No Reasonable Jury Could Have Found Literal Infringement Of The 376 and 989 Patents And A New Trial Is Warranted.....	5
a) PrimaFit Does Not Have A Support “Distinct From and Proximate To” The Reservoir	5
b) PrimaFit Does Not Include An “Elongated Opening”	6
c) PrimaFit Does Not Have A “Casing,” Much Less A Fluid Impermeable One	7
4. PureWick Did Not Establish Indirect Infringement.....	8
5. A New Trial Is Warranted Due To Prejudicial Missteps By PureWick Including Its Product To Patent Figure Comparisons	8
B. JMOL And A New Trial On The 407 Patent Should Be Granted	12
1. PrimoFit Does Not Have a “Wicking Material” As Its Top Layer	12
2. PrimoFit Does Not Have a “Chamber of Voice Space”, Much Less One “Having a Port for Receiving a Tube...”	14
III. JMOL AND A NEW TRIAL ON INVALIDITY IS WARRANTED	15
A. PureWick’s Prejudicial And Legally Incorrect Arguments About The State Of The Art Warrant A New Trial	16

B.	PureWick Provided No Witness Testimony or Evidence Rebutting Anticipation Or Obviousness of the 376/989 Patents By Van Den Heuvel	17
C.	The Jury’s Finding of No Obviousness Of The 407 Patent Is Not Supported by Substantial Evidence And Prejudicial Statements Misled The Jury	18
IV.	JMOL AND A NEW TRIAL ON WILLFULNESS SHOULD BE GRANTED	20
A.	PureWick Offered No Evidence of Any Post-Issuance Willfulness.....	20
B.	Years-Old “Pre-Issuance” Activity Could Not Establish Willfulness	21
1.	Knowledge Of An Old Patent Application Is Not Willfulness	22
2.	PureWick’s Years-Old Copying Theories Did Not Establish That Sage Copied Any Product, Much Less A Patented One.....	23
C.	A New Trial On Willfulness Is Warranted Based On Improper, Unsupported, And Misleading Arguments Made By PureWick At Trial.....	26
V.	JMOL AND A NEW TRIAL, OR A REMITTITUR, ON DAMAGES SHOULD BE GRANTED	27
A.	Despite Its Burden, PureWick Never Rebutted Evidence of Sage’s Acceptable, Noninfringing Design Alternative	27
B.	The Testimony of PureWick’s Expert Demonstrates the Existence of Acceptable NIAs and Inability to Prove Marketing Capability	28
C.	There Was No Apportionment And The Trial Evidence Did Not Establish Demand for the Patented Product.....	29
VI.	JMOL THAT PUREWICK’S “BLUE SILICONE SHELL” PRODUCT IS NOT COVERED BY ITS PATENTS SHOULD BE GRANTED.....	30
VII.	CONDITIONAL MOTION TO AMEND THE JUDGMENT	30

TABLE OF AUTHORITIES

CASES

<i>Acceleron, LLC v. Dell Inc.</i> , No. 1:12-cv-4123-TCB, 2022 WL1087683 (N.D. Ga. Mar. 7, 2022)	21
<i>Akamai Techs. v. Limelight Networks</i> , 797 F.3d 1020 (Fed. Cir. 2015)	5
<i>Allergan, Inc. v. Apotex Inc.</i> , 754 F.3d 952 (Fed. Cir. 2014)	18
<i>Amazon.com, Inc. v. Barnesandnoble.com, Inc.</i> , 239 F.3d 1343 (Fed. Cir. 2001)	24, 26
<i>Amgen Inc. v. Sanofi</i> , No. 14-1317-RGA, 2019 WL 4058927 (D. Del. Aug. 28, 2019)	26
<i>Bayer Healthcare LLC v. Baxalta Inc.</i> , 989 F.3d 964 (Fed. Cir. 2021)	20, 21
<i>bioMerieux, S.A. v. Hologic, Inc.</i> , No. 18-21-LPS, 2020 WL 759546 (D. Del. Feb. 7, 2020)	22
<i>Bioverativ Inc. v. CSL Behring LLC</i> , 17-914-RGA, 2020 WL 1332921 (D. Del. Mar. 23, 2020)	23, 24
<i>Bullen v. Chaffinch</i> , 336 F. Supp. 2d 342 (D. Del. 2004)	3
<i>Catalina Lighting v. Lamps Plus</i> , 295 F.3d 1277 (Fed. Cir. 2002)	9, 23, 26
<i>Commil USA, LLC v. Cisco Sys.</i> , 575 U.S. 632, 135 S. Ct. 1920 (2015)	8
<i>Conopco, Inc. v. May Dep't Stores Co.</i> , 46 F.3d 1556 (Fed. Cir. 1994)	22
<i>DePuy Spine v. Medtronic Sofamor Danek</i> , 567 F.3d 1314 (Fed. Cir. 2009)	19
<i>Ericsson, Inc. v. D-Link Sys., Inc.</i> , 773 F.3d 1201 (Fed. Cir. 2014)	30
<i>Finjan, Inc. v. Symantec Corp.</i> , No. 10-CV-593-GMS, 2013 WL 5302560 (D. Del. Sept. 19, 2013), <i>aff'd</i> , 577 F. App'x 999 (Fed. Cir. 2014)	8
<i>Fujitsu v. Netgear</i> , 620 F.3d 1321 (Fed. Cir. 2010)	5

<i>GN Netcom, Inc. v. Plantronics, Inc.</i> , 930 F.3d 76 (3d Cir. 2019)	17
<i>Grain Processing Corp. v. Am. Maize-Prods. Co.</i> , 185 F.3d 1341 (Fed. Cir. 1999)	27, 28
<i>Hutchins v. Zoll Med. Corp.</i> , 492 F.3d 1377 (Fed. Cir. 2007)	6
<i>iFIT Inc. v. Peloton Interactive, Inc.</i> , No. 21-507-RGA, 2022 WL609605 (D. Del. Jan. 28, 2022).....	22
<i>Interlace Med., Inc. v. Hologic, Inc.</i> , No. 10-10951, 2012 WL 3560811 (D. Mass. Aug. 17, 2012)	24
<i>Lightning Lube, Inc. v. Witco Corp.</i> , 4 F.3d 1153 (3d Cir. 1993)	3
<i>Limelight Networks v. Akamai Techs.</i> , 572 U.S. 915 (2014).....	5
<i>MasterObjects, Inc. v. Google, Inc.</i> , No. C 11-1054, 2013 WL 12177460 (N.D. Cal. May 2, 2013)	24
<i>Micro Chemical, Inc. v. Lextron, Inc.</i> , 318 F.3d 1119 (Fed. Cir. 2003)	29
<i>Norian Corp. v. Stryker Corp.</i> , 363 F.3d 1321 (Fed. Cir. 2004)	21, 25
<i>Nox Med. Ehf v. Natus Neur.</i> , No. 15-709-RGA, 2018 WL6629704 (D. Del. Apr. 12, 2018).....	26
<i>Optolum, Inc. v. Cree, Inc.</i> , No. 1:17CV687, 2021 WL5505794 (M.D.N.C. Nov. 24, 2021)	21
<i>OSI Pharms., LLC v. Apotex Inc.</i> , 939 F.3d 1375 (Fed. Cir. 2019)	18
<i>Pannu v. Iolab Corp.</i> , 155 F.3d 1344 (Fed. Cir. 1998)	3
<i>Perkin-Elmer v. Computervision</i> , 732 F.2d 888 (Fed. Cir. 1984)	3
<i>Pfaff v. Wells Elecs</i> , 525 U.S. 55 (1998).....	16
<i>Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.</i> , 711 F.3d 1348 (Fed. Cir. 2013)	10

<i>Presidio Components, Inc. v. Am. Tech. Ceramics Corp.</i> , 875 F.3d 1369 (Fed. Cir. 2017)	27, 28
<i>Rite-Hite Corp. v. Kelley Co.</i> , 56 F.3d 1538 (Fed. Cir. 1995)	27
<i>Roche Diags. Corp. v. Meso Scale Diags.</i> , 503 F. Supp. 3d 156 (D. Del. 2020).....	4
<i>Simone v. Golden Nugget Hotel & Casino</i> , 844 F.2d 1031 (3d Cir. 1988)	14
<i>Sonos, Inc. v. D&M Holdings Inc.</i> , No. CV 14-1330-WCB, 2017 WL 5633204 (D. Del. Nov. 21, 2017).....	23, 24, 25
<i>Star Tech. Grp., Inc. v. Testerion, Inc.</i> , No. 99-1168, 1999 WL 693829 (Fed. Cir. 1999)	9, 23
<i>State Indus. v. A.O. Smith Corp.</i> , 751 F.2d 1226 (Fed. Cir. 1985)	22, 24
<i>Trebro Mfg. v. FireFly Equip., LLC</i> , 748 F.3d 1159 (Fed. Cir. 2014)	19
<i>Trs. of Columbia Univ. v. Illumina, Inc.</i> , 620 F. App'x 916 (Fed. Cir. 2015)	16
<i>Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.</i> , 774 F.3d 968 (Fed. Cir. 2014)	16
<i>Uber Techs., Inc. v. X One</i> , 957 F.3d 1334 (Fed. Cir. 2020)	18
<i>UCB, Inc. v. Watson Labs., Inc.</i> , No. 14-1083-LPS-SRF, 2017 WL 11646645 (D. Del. Nov. 22, 2017)	16
<i>W. Union Co. v. MoneyGram Payment Sys.</i> , 626 F.3d 1361 (Fed. Cir. 2010)	19
<i>Wechsler v. Macke Int'l Trade, Inc.</i> , 486 F.3d 1286 (Fed. Cir. 2007)	27
<i>Woodson v. Scott Paper Co.</i> , 109 F. 3d 913 (3d Cir. 1997)	4
<i>Zenith Lab'ys, Inc. v. Bristol-Myers Squibb Co.</i> , 19 F.3d 1418 (Fed. Cir. 1994)	9
STATUTES	
35 U.S.C. §102.....	16

RULES

Fed. R. Civ. P. 50.....	1, 3
Fed. R. Civ. P. 59.....	1

* Unless otherwise noted, all emphases herein have been added. Citations and quotations in case citations have generally been omitted.

**Trial exhibits shall be provided separately to the Court in accordance with the Court's Preferences & Procedures for Civil Cases. Other exhibits, including trial demonstratives, are being submitted herewith.

Pursuant to Fed. R. Civ. P. 50 and 59, Sage moves for judgment as a matter of law (JMOL) and a new trial on issues of infringement, invalidity, willfulness, and damages. Sage also contingently seeks to amend the judgment (D.I. 320) pursuant to Rule 59(e).

NATURE AND STAGE OF PROCEEDINGS

Trial in this matter occurred March 28 to April 1, 2022. Opening statements were presented over certain objections. (Tr. 2-8, 94-158; PDX1; SDXO; SDX1.) PureWick's case-in chief included testimony from Camille Newton (Tr. 161-249, 254-75) who testified about "hundreds and hundreds" of PureWick versions (Tr. 173); Ray Newton (Tr. 288-325) who testified that there were "a hundred" brown tape products that "were all different" (Tr. 291, 297); Robert Sanchez (Tr. 277-287); John Gohde (Tr. 342-380) who testified that many hospitals did not use the products and did not demand patented features (Tr. 369-370); infringement expert John Collins (Tr. 424-540; PDX4); Edward Yun (Tr. 389-424); and damages expert Gregory Leonard (Tr. 541-580). The only Sage employee that testified was Kristin Sexton (Tr. 326-342), a nurse with no knowledge of any PureWick patents and no involvement in PrimaFit engineering (Tr. 329, 337-338).

During PureWick's case-in-chief, no witness testified that Sage or any party used PrimaFit. No witness testified that Sage knew about any patents or acted improperly after the patents issued in 2019. Though there was testimony that Sage purchased PureWick products in 2016 (Tr. 216), there was no evidence indicating what those products were, much less that any person in Sage product development had access to them or that they were patented. PureWick rested, and Sage moved for JMOL on a number of issues and the Court reserved ruling. (Tr. 580, 653-666.)

Sage thereafter presented its case-in-chief consisting of testimony from Sage PrimaFit engineer Brett Blabas (Tr. 581-635; SDX3; DTX165, 187, 772, 903) who testified she had no knowledge of any PureWick patents or patent applications and was not aware of which PureWick version product she had seen (Tr. 608, 610); PrimaFit engineer Brian Ecklund (Tr. 635-652;

DTX617, DTX680); marketing employee Kelsey Paskal (Tr. 667-695; DTX193, 196, 755; PTX36, 37, 42); Sage attorney Nick Alexander (Tr. 877-888); expert Diane Newman who testified on the state of the art and obviousness in view of Suzuki (Tr. 696-746; SDX5; DTX6, 7, 8, 9, 16, 17, 21, 29, 523A, 525A); expert Donald Sheldon who testified about noninfringement and invalidity in view of Van Den Heuvel (Tr. 761-873; SDX6; JTX1; DTX12, 13, 21, 532B), and damages expert Vincent Thomas (Tr. 889-925; SDX11; DTX557A-J). Third parties, Jason Bobay (Tr. 747-759; DTX198, 753) and Laura Shaw (Tr. 874-876; DTX520), also testified. Over Sage's objections (e.g., Tr. 836, 839-842), PureWick crossed Sage's experts on whether prior art patents resulted in commercial products (e.g., Tr. 840-842) and whether references were before the PTO (e.g., Tr. 847-849). Sage rested and renewed its JMOL and moved for JMOL of invalidity. (Tr. 933-35.)

PureWick then presented testimony from its invalidity expert Arrigo Jezzi, who did not provide any opinion on Van Den Heuvel (Tr. 939-967; DTX628), as well as additional testimony from Leonard (Tr. 968-984.) Sage renewed its JMOL motions and the Court reserved. (Tr. 984.)

Finally, Sage presented rebuttal from expert Sheldon (Tr. 985-987; SDX12a.) Sage rested and renewed its JMOL motions. (Tr. 987, 992; D.I. 325 at 1-2.)

A conference on jury instructions was held. (Tr. 998-1075.) In light of the trial, Sage requested clarifying instructions on, e.g., copying and lack of relevance of commercial products to invalidity, which were denied. (Tr. 1014-15, 1039-40.) The parties presented closing arguments (Tr. 1143-1228; PDX8; SDXC) with Sage objecting to PureWick demonstratives (Tr. 1090-95).

On April 1, the jury found that Sage willfully infringed the 376 and 989 Patents and infringed the 407 Patent, found against Sage on invalidity, and awarded \$26,215,545 in lost profits damages for PrimaFit and \$1,799,193 in reasonable royalty for PrimoFit. (D.I. 316.)

SUMMARY OF THE ARGUMENT AND ARGUMENT

No reasonable jury could find that Sage directly or indirectly infringed the patents-in-suit

or that they were not invalid. Contrary to the jury's findings, there was no evidence that any entity practiced the methods claimed in the 989 Patent. PureWick's infringement theories were legally and factually wrong and, misled by PureWick's inappropriate trial themes, the jury ignored failures of proof and overlooked the evidence of noninfringement and invalidity. Additionally, no reasonable jury could find willfulness of the 376 or 989 Patents, and the jury's findings are against the clear weight of the evidence. PureWick introduced no evidence of knowledge of the patents or Sage's intent. There was no evidence of any post-issuance wrongful conduct and pre-issuance allegations were legally irrelevant. The jury's damages award was contrary to law and facts because no reasonable jury could find that PureWick was entitled to lost profits. PureWick failed to prove its blue silicone products were covered by its patents. The jury's findings were against the weight of the evidence and evidentiary rulings were erroneous and prejudicial. JMOL and a new trial on infringement, invalidity, willfulness and damages is warranted as well as remittitur.

I. LEGAL STANDARDS FOR JMOL AND NEW TRIAL

JMOL is appropriate when "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1), 50(b). The moving party "must show that the jury's findings...are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998); *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). "Substantial evidence" is "such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer v. Computervision*, 732 F.2d 888, 893 (Fed. Cir. 1984).

The Court may grant a new trial where, e.g., "the jury's verdict is against the clear weight of the evidence," "substantial trial errors were made," or "damages are excessive." *Bullen v. Chaffinch*, 336 F. Supp. 2d 342, 347 (D. Del. 2004); *Woodson v. Scott Paper Co.*, 109 F. 3d 913,

936 (3d Cir. 1997). “[T]he standard for granting a new trial is less rigorous than the standard for [JMOL], in that the court need not view the evidence in the light most favorable to the verdict winner.” *Roche Diags. Corp. v. Meso Scale Diags.*, 503 F. Supp. 3d 156, 166 (D. Del. 2020).

II. JMOL AND A NEW TRIAL ON INFRINGEMENT IS WARRANTED

No reasonable jury could find infringement of the patents-in-suit and its findings were against the weight of the evidence.¹ Numerous prejudicial rulings further influenced the verdict. JMOL of no infringement should be granted and/or a new trial ordered on all liability issues.

A. JMOL And A New Trial On The 376 And 989 Patents Should Be Granted

1. There Was No Evidence That Sage Practiced The 989 Patent

Claims 1 and 6 of the 989 patent, which issued in August 2019, recite various method steps of using the urine collection device including, e.g., “disposing” the device “with a female user” and “coupling the...tube” to vacuum. (JTX3.) Yet, the jury found that Sage directly infringed the claims (D.I. 316 (Q1)), even though PureWick did not present any evidence that Sage itself performed any method steps. (Tr. 425-505, 528-540.) Sage is not a “hospital” and there is no record evidence that Sage performed these steps. (*Id.*) JMOL or a new trial should be granted.

2. There Was No Evidence of Direct Infringement Of The 989 Patent By Any Entity (Much Less After August 2019)

The jury found that Sage indirectly infringed the 989 Patent (D.I. 316 (Q2)) even though PureWick failed to identify a single instance of direct infringement—a prerequisite for indirect infringement. (Tr. 654.) PureWick never introduced evidence that any method step was (1) actually performed, let alone (2) by a single entity (3) after August 2019. PureWick argued that it did not

¹ Sage reserves its rights as to the rulings on claim construction. (*See, e.g.*, D.I. 128; D.I. 308 at 12 n.3; D.I. 285 at 20 n.9; Tr. 1019.) Had the claims been construed as Sage proposed (particularly on the “casing” and “chamber” elements), there would be no infringement. JMOL and/or a new trial on infringement is warranted under the correct claim constructions.

need to prove direct infringement because following the PrimaFit IFU allegedly resulted in infringement. (Tr. 469-470.) This was wrong because, **first**, “it is not enough to simply show that a product is capable of infringement; the patent owner must show evidence of specific instances of direct infringement.” *Fujitsu v. Netgear*, 620 F.3d 1321, 1329 (Fed. Cir. 2010). **Second**, PureWick never adduced evidence in its case-in-chief that Sage instructed anyone to follow the IFU; thus, JMOL should have been granted for that reason alone. (Tr. 935-936.) **Third**, there is no evidence that the IFU instructed a single entity to perform each step. (PTX34; JTX14); *Limelight Networks v. Akamai Techs.*, 572 U.S. 915, 921 (2014); *Akamai Techs. v. Limelight Networks*, 797 F.3d 1020, 1022 (Fed. Cir. 2015). **Fourth**, there is no evidence that anyone actually followed the IFU—much less a single entity—to perform the claimed method steps.² PureWick’s infringement allegations were hypothetical. (Tr. 1165, 659.) JMOL or a new trial should be granted.

3. No Reasonable Jury Could Have Found Literal Infringement Of The 376 and 989 Patents And A New Trial Is Warranted

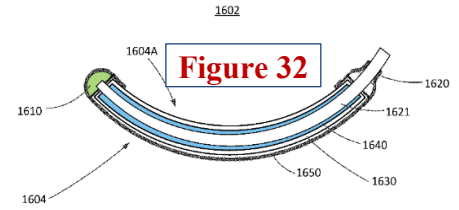
PrimaFit is missing numerous claim elements as a matter of law. Substantial evidence does not support the jury’s verdict and the verdict is against the weight of the evidence.

a) PrimaFit Does Not Have A Support “Distinct From and Proximate To” The Reservoir

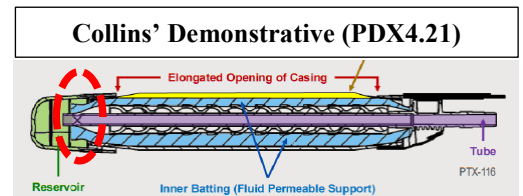
No reasonable jury could find that PrimaFit has a “support [that] is distinct from and at least proximate to the fluid reservoir” required by the independent claims. (JTX2; JTX3.) Importantly, during prosecution, this limitation was identified as the allegedly novel aspect of the invention and was added to the claims to avoid the prior art. (JTX5A at 3-4, 7-8; JTX6A at 3-4; Tr. 778-780.) PureWick referenced Figure 32 and argued that its invention “explicitly provides the

² Sage requested a jury instruction on single-entity infringement, which was denied. (Tr. 988-991, 997-1001.) This warrants a new trial as the jury should have been able to consider whether PureWick established a single entity practiced the method steps. *Limelight*, 572 U.S. at 921.

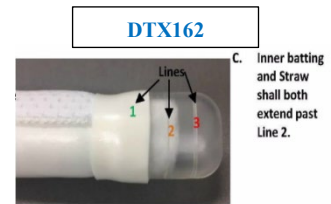
reservoir [green] does not include the permeable membrane and permeable support [blue]” and that “the reservoir does not contain the fluid permeable support...”³ (JTX5 at 424; JTX6 at 587-588.) No reasonable jury could find PrimaFit satisfies the limitation because the reservoir in PrimaFit does include and does contain the support. *Hutchins v. Zoll Med.*, 492 F.3d 1377, 1381 (Fed. Cir. 2007).



As shown in PureWick’s demonstrative (PDX4.21 (red circle added)), the batting (blue) is in the reservoir (green). (PDX4.2,17,19,21; *see also* PDX4.19 below.) Indeed, the reservoir extends around the end of the batting and above and below the tube (purple). Collins testified



that PrimaFit meets the limitation “a tube having a first end *disposed in the reservoir*”; thus the batting is necessarily in the reservoir as well. (Tr. 458.) Thus, no reasonable jury could find that the element is satisfied as the reservoir does not include or contain the support within it.⁴ The substantial evidence at trial repeatedly proved the point with no contrary evidence. (JTX14; Tr. 604, 768; DTX162 at 4; PTX116; PDX4.2, 17, 19, 21.) DTX162, Sage’s manufacturing instructions, require the batting to extend into the reservoir as shown here. (*Id.* at 4; PTX116 at3; PDX4.17, 21; Tr. 769.)



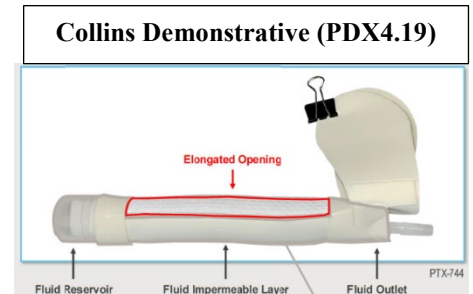
b) PrimaFit Does Not Include An “Elongated Opening”

No reasonable jury could find that the PrimaFit has a “casing . . . defining a longitudinally elongated opening between the fluid reservoir and the fluid outlet.” PureWick alleged that the

³ Sage moved for summary judgment of noninfringement on this limitation. (D.I. 204 at 9-10.)

⁴ PureWick later implied that space inside the cap is the claimed “reservoir,” which is a newly alleged theory. (Compare Tr. 1162:10-20 with, e.g., D.I. 210, Ex. 31 at ¶110 (“the cap is a fluid reservoir that is coupled to the foam backing.”).) To the extent it argues a new theory which would be inappropriate at this stage, PrimaFit would be missing numerous additional claim elements under that new theory, e.g., “fluid impermeable layer coupled to the fluid reservoir” and “elongated opening” defined “between the fluid reservoir and the fluid outlet.” (Tr. 1196.)

PrimaFit has a “casing” comprised of the foam back, cap, and two pieces of tape and that the alleged “elongated opening” is shown in this demonstrative. (Tr. 448; PDX4.19.) But no reasonable jury could find there is an “opening” in that area. An “opening” is open, but the area labeled as an “opening” by Collins is closed. There is fabric sewn to the foam back, creating a physical barrier without an opening. (Tr. 598-599, 603, 772, 449-50; DTX162 at 2; PTX116.) This is consistent with the specification that depicts a casing having an elongated opening and describes the casing’s opening as a physical opening through which components are inserted and not merely “open to urine flow” as PureWick advocated in closing. (*See e.g.*, JTX2 at 25:58-66 (“the permeable membrane 1830 and the permeable support 1840 can then be inserted through the elongated opening 1804A of the impermeable casing 1804”); 23:46-49.) Notably, the substantial weight of the evidence was that this area was deliberately designed to be closed—rather than open—to prevent patient’s skin from being trapped within it. (Tr. 603, 682, 732, 772-773.)



c) PrimaFit Does Not Have A “Casing,” Much Less A Fluid Impermeable One

No reasonable jury could find that the PrimaFit has a “fluid impermeable casing.” (JTX2; JTX3.) The various unrelated components PureWick identified as the “casing” (the foam back, cap, and two pieces of tape) do not form an “outer cover” as the term was construed nor would a POSA understand them to do so while arbitrarily excluding other outer components including the absorbent fabric that is integral with the foam back. (Tr. 770-773, 603.)⁵ Additionally, the alleged casing is not “impermeable” because the PrimaFit was intentionally designed with a number of

⁵ As discussed above, under the proper construction, there is no casing in the PrimaFit because the 376 and 989 patents state that taping a backing to a reservoir cap is not a casing. (JTX2 at 26:43-45; JTX3 at 25:36-38; D.I. 105 at 53-60, 65-67; D.I. 128.) The claim construction rulings are reserved for appeal as infringement could not be found under that construction.

openings that are liquid permeable. (Tr. 604-605; JTX14.) PrimaFit assembly instructions and specification require gaps. (*Id.*; DTX162 at 9 (“verify small gap is visible”); PTX116 at 3 (“visible gap should be seen”).) Sage’s expert Sheldon tested the product and determined that liquid flows through the gaps, which means it is not impermeable. (Tr. 771-772.) PureWick did not contest those tests or provide contrary testing. (Tr. 500.) Instead, PureWick’s counsel argued on closing that, despite the claims, the product can be permeable because the patent depicts an embodiment with a “vacuum relief opening.” (Tr. 1163-1164.) But the specification cannot change whether PrimaFit’s “casing” is impermeable under the Court’s construction. Moreover, the relief opening was for *air* to exit the device, not liquid. (JTX2, 6:12-28.) Attorney argument about a specification is not evidence by which the jury could find infringement. *Finjan v. Symantec*, No. 10-CV-593-GMS, 2013 WL 5302560, at *25 (D. Del. Sept. 19, 2013), *aff’d*, 577 F. App’x 999 (Fed. Cir. 2014).

4. PureWick Did Not Establish Indirect Infringement

There is no direct infringement of the 376 or 989 Patents, and thus there can be no indirect infringement. To prove indirect infringement, PureWick was required to further prove knowledge of the patents and knowledge of infringement, i.e., that “Sage knew that the actions of third parties would infringe” or that a component “was especially made or adapted for use as an infringement of the claim” for contributory infringement. (D.I. 314, 19-20.) Mere knowledge of the patents is not enough. *Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632, 640, 135 S. Ct. 1920, 1926 (2015). Yet, as discussed in Section IV.A., PureWick proved neither knowledge of the patents or any intent to infringe. Thus, JMOL or a new trial is warranted.

5. A New Trial Is Warranted Due To Prejudicial Missteps By PureWick Including Its Product To Patent Figure Comparisons

PureWick repeatedly attempted to prove infringement and improper copying by comparing PrimaFit with patent figures and PureWick’s products, which warrants a new trial. “Infringement

is to be determined by comparing the asserted claim to the accused device, not by comparing the accused device to the figures of the asserted patent.” *Catalina Lighting v. Lamps Plus*, 295 F.3d 1277, 1286 (Fed. Cir. 2002). “[I]t is error...to compare...the accused product or process with the patentee's commercial embodiment....” *Zenith Lab’ys, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994); *Star Tech. Grp., Inc. v. Testerion*, No. 99-1168, 1999 WL 693829, at *6 (Fed. Cir. 1999) (“infringement is determined by comparing the accused device to the claims, rather than comparing the accused device to the figures of the patent specification.”). Thus, PureWick’s comparison of PrimaFit to patent figures or plaintiff’s products was legally improper.

Sage filed a MIL to preclude PureWick from comparing the accused products to patent figures or products. (D.I. 286-20.) At the pretrial conference, the Court asked: “tell me in what instance or for what purpose you would be putting up a picture from the patent and comparing it to their product?” and PureWick represented “I’m not sure that there is any instance that we plan to do that, Your Honor” and even stated it would not be done for “copying.” (D.I. 296 at 21, 22.) The Court held that PureWick could not make the comparison but if it needed to do so for some reason should seek permission “outside the presence of the jury.” (D.I. 303 at 3 n.4, n.5.) Yet, at trial, PureWick repeatedly compared PrimaFit to patent figures and products without ever asking outside the presence of the jury. Sage objected multiple times and was overruled each time. (*See, e.g.*, Tr. 115-116 (“you made a ruling that they were not supposed to do that....he is going through the elements of the claims and he is saying casing, casing, reservoir, reservoir.”; Tr. 537-539 (“he’s put up a picture of a patent ...He’s now talking about our product while he has a picture of the patent up.”).) The comparisons were improper to prove either infringement or copying. *See infra*.

PureWick took these rulings as carte blanche to show the jury Figures 36 to 38 of the patents at every turn and prove infringement by patent figure and product comparison:

- In its Opening, PureWick compared features of the PureWick product to PrimaFit in discussing infringement, asserting elements were present. (Tr. 114-116 (“[T]hey’re going to assert they don’t infringe...The way it works as you see in the video is the urine comes in through this surface, *both in theirs and in ours*, it then gathers at the bottom *in theirs here, and in ours, here.*”) Sage’s objections were overruled. (*Id.*)
- PureWick’s infringement expert Collins repeatedly interwove discussion of the PrimaFit device, Figures 36 to 38, and the PureWick device. (*See, e.g.*, PDX4 at 2 (PrimaFit), 3 (PureWick), 7-13 (Figs. 36-38), 15-16 (PureWick), 17+ (PrimaFit); Tr. 429-43 (PrimaFit), 430-433 (PureWick), 430-439 (embodiments of 376/989 patents), 439-446 (PureWick), 446-467 (PrimaFit).) As discussed below, Sage was precluded from disputing these improper correlations.
- When questioning Collins about infringement issues, counsel for PureWick displayed a demonstrative showing the embodiment of Figures 36 to 38 (PDX4.12) and asked questions related to the cross examination concerning non-infringement from moments prior. (Tr. 536-540.) Again, Sage’s objections were futile and were overruled. (*Id.*)
- PureWick’s counsel, completely unfettered having had all objections repeatedly overruled, directly compared Figures 37-38 to the PrimaFit to prove infringement, arguing how “persuasive” it was that the PrimaFit infringed in view of these figures. (Tr. 1161-1163 (“even more persuasive, this is the embodiment I showed you where the casing is made out of a component...”); 1163-65.) Slides depicted Figures 37-38 and included the header “Infringement” along with claim terms. (PDX8.64, 8.70.) Immediately after was a slide of the PrimaFit (PDX8.65), making a direct comparison of the product with the patent figure. (*See* PDX8.58-70.)
- Regarding “distinct from ... and proximate to,” PureWick’s counsel told the jury that figures showed how “fabric tucks into the cap....[A]t the end of the cap [in the figure], there is a reservoir where urine can accumulate. This is the kind of argument people come up with when they know they infringe.” (PDX8.64; Tr. 1163-64.)
- Counsel also contended—pointing to the figure—that the “impermeable support goes into the cap, but there is empty space. He’s like pay no attention to the fact that you have a patented embodiment whereby the way the tape is holding on to the top wicking material, and then he says okay,... Don’t pay any attention to the fact that the patent is showing that.” (Tr. 1218.) Counsel’s assertions were particularly egregious given that there was no evidence that the embodiment has “space” at the end of the device.⁶
- Regarding the “elongated opening” limitation, counsel also argued infringement by patent figures: “The elongated opening, okay, I showed you, I showed you, I said here,

⁶ The jury was instructed that all unconstrued limitations were to be given their “ordinary meaning.” (D.I. 314 at 14.) But the jury was not presented the ordinary meaning in these arguments. *See Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1361 (Fed. Cir. 2013). The meaning PureWick assigned at trial is also incorrect as a matter of law.

in the patent [figure], you have elongated opening through which fluid goes over.” (Tr. 1219; *see* 1164 (“[I]n this embodiment [Figure 38] where the tape is adhered to the wicking material, its not like – its not open the way they say . . .”).)⁷

By repeatedly comparing PrimaFit to patent figures and to PureWick’s product, PureWick improperly implied that Sage “infringed” the figures or the product, rather than the claims. (*See* PDX1.16-18, PDX8.20, PTX158 at 1-2, 67.) These comparisons were legally wrong, causing the jury to find willful infringement based on patent figure comparisons and not the claims.

Importantly, when Sage attempted to address these comparisons by, e.g., cross-examining PureWick’s expert about the figures, Sage was precluded from providing evidence to the jury of what the patent said that figures disclose. (Tr. 533-535; *see also* D.I. 287 at 5.) Thus, the error of PureWick’s inappropriate comparisons was compounded. Simply put, Sage was not permitted to refute PureWick’s infringement by patent figure arguments by presenting the undisputable fact that the 376 and 989 patents themselves do not describe the embodiment in Figures 36 to 38 as a “casing” or from referencing the patent text that states: “In some implementations, rather than including an impermeable casing, an assembly can include an impermeable backing that includes adhesive tape.” (JTX2 at 26:43-45; Tr. 534-535.) In the end, PureWick was allowed to represent that Figures 36 to 38 was a “casing” (even though the patent never called it one) and compare PrimaFit to that alleged “casing” despite law prohibiting such comparisons. (Tr. 435-448.) This error permeated every aspect of the trial—infringement, willfulness, damages. A new trial is warranted to cure these prejudicial errors.

As discussed in Section IV.C., PureWick was permitted to make numerous other prejudicial arguments including that Sage allegedly engaged in improper behavior including “copying” (even though there was no evidence that Sage had any patented product). These

⁷ This construction proffered during closing was also incorrect as discussed above.

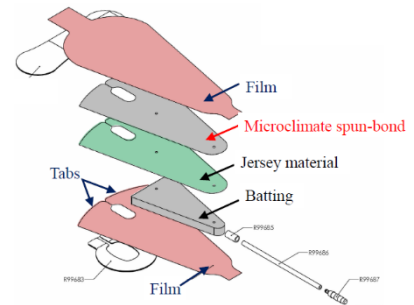
unsupported allegations further improperly tainted the jury to suggest finding infringement contrary to the evidence. A new trial is warranted on infringement for the same reasons.

B. JMOL And A New Trial On The 407 Patent Should Be Granted

The 407 patent is directed to a male urine collection device with a particular configuration: a patient-facing “wicking material” (14) disposed on a “porous material” (12) with a portion of the “porous material” secured to an “impermeable material” (16). (JTX4 at Claim 1, Fig. 2.) A “chamber of void space [is] positioned . . . between the flexible layer of porous material and the flexible layer of impermeable material, the chamber . . . having a port (22) for receiving a tube to transport urine.” (*Id.*) No reasonable jury could have found that PrimoFit satisfies these imitations, and the jury’s verdict is against the weight of the evidence.

1. PrimoFit Does Not Have a “Wicking Material” As Its Top Layer

PrimoFit includes four materials: a patient-facing microclimate spun-bond layer, a jersey fabric beneath the microclimate layer, and a batting, all of which are between two layers of plastic film. (DTX680; Tr. 635-652, 819-820.) PureWick alleged that the microclimate layer is the “wicking material.” (Tr. 486) No reasonable jury could have found that it is. The Court construed “wicking material” as “an article that moves moisture by capillary action from one surface of the article to the other.” (Tr. 1108.) Rather than being a wicking material, the PrimoFit’s microclimate material is a water-repellant material made from polypropylene (a type of plastic) that allows urine to pass through it to the jersey layer beneath without wicking. (Tr. 644-645, 818-822; D.I. 204 at 3.)



In its case-in-chief, PureWick presented no evidence to carry its burden of showing that the microclimate layer was a wicking material. For example, unlike his analysis for PrimaFit which relied on wicking tests for that material (Tr. 464-465), Collins performed no testing to determine

if the microclimate material in PrimoFit was wicking and did not offer any evidence that the material transported fluid by capillary action. (Tr. 485-487, 502-503, SDX12A.13-16.) Rather, Collins pointed to a marketing sheet (PTX95) that referred to PrimoFit having an “ultra soft wicking fabric.” (Tr. 486-487.) But PTX95 depicts all four PrimoFit materials and does not state that the microclimate layer in particular is wicking. (*Id.*; Tr. 822.) The “ultra soft fabric” in PrimoFit is the jersey fabric (the item that PureWick contended was the “porous material”)—not the thin polypropylene microclimate layer. (*See* PTX97 at 1, PTX98 at 1; Tr. 462-467, 822.)

Collins also referenced a “hydrophilic” treatment of the microclimate material. (Tr. 485-487.) But Collins had no idea where that treatment was applied—much less how it proved wicking. (Tr. 502-504 (“Q. What has the hydrophilic, is it on the top, the bottom, throughout? A. Typically these are covered throughout. Q. So you don’t know actually with respect to this material where the hydrophilic treatment is, do you? A. I am pretty sure ...”).) The evidence showed that Collins’ assumption was wrong—the hydrophilic treatment is not “covered throughout.” (Tr. 643-644 (Q. Is the spun bond polypropylene covered throughout with the hydrophilic treatment? A. No.”).) In any case, Collins’ bare testimony, coupled with a marketing document about other layers, is not substantial evidence that the microclimate material “moves moisture by capillary action....” No reasonable jury could have found infringement after PureWick’s case-in-chief. (Tr. 653-666.)

Sage provided the only evidence relevant to the Court’s construction. Sage’s expert (Sheldon) tested the microclimate material using a vertical wicking test (used by PureWick for wicking in the PrimaFit, Tr. 464-465) to determine whether it satisfied the Court’s construction. (Tr. 818-822; DTX532b.) The test definitively showed the material did not wick liquid at all. (*Id.*) The weight of the evidence showed that the material is a non-wicking material consistent with non-wicking materials used as top layers in diapers. (Tr. 819.) PureWick never questioned Sheldon

about his testing. (Tr. 829-871.) Thus, no reasonable juror could have found in favor of PureWick on infringement and JMOL should have been granted at the close of Sage’s case. (Tr. 928-939.)

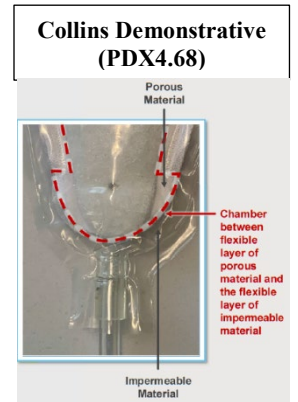
PureWick later introduced testing evidence from its other expert, Jezzi. (Tr. 946-952.) But Jezzi’s testing (which Sage unsuccessfully moved to exclude, *see* D.I. 198, 205) did not establish that the microclimate material moves moisture by capillary action. (Tr. 959-966.) Rather than isolating and testing the microclimate material, Jezzi incorrectly tested all four materials in the product together. (Tr. 959.) Jezzi admitted that the tests did not establish that wicking was attributable to the microclimate material. (Tr. 960 (“Q. But this test doesn’t show that the top layer is wicking, it just shows there is wicking somewhere in the device; correct? A. That shows wicking through the entire device. Q. So that doesn’t tell you anything about the top layer; right? A. That’s correct.”). Jezzi also performed a “splat” test, which was not a recognized wicking test but a made-up test that violated standard procedures. (DTX628; Tr. 962-966 (“Q... [Y]ou’re supposed to suspend the material...and see how it spreads, correct? A. Yes”).) Jezzi’s splat test did not show wicking but only that fluid spreads if pressed—whether or not it was wicking. (Tr. 986-987.)

Accordingly, because Sage introduced evidence that the microclimate material is not a wicking material and PureWick introduced no valid evidence to the contrary, no reasonable jury could have found for PureWick on this issue and JMOL and/or a new trial should be granted. *See Simone v. Golden Nugget Hotel & Casino*, 844 F.2d 1031, 1034 (3d Cir. 1988).

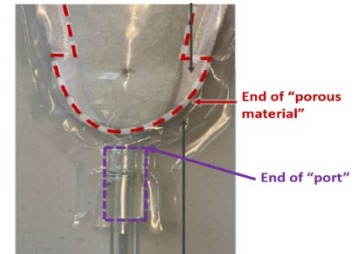
2. PrimoFit Does Not Have a “Chamber of Voice Space”, Much Less One “Having a Port for Receiving a Tube...”

The entirety of PureWick’s case-in-chief evidence that PrimoFit has a “chamber of void space positioned within the interior...between the...porous material and...impermeable material and configured to collect urine for transport” is a single answer referring to a demonstrative where Collins refers to an “empty space” that he claims exists between the white porous material and the

clear impermeable material. (PDX4.68; Tr. 490 (“you can see the red dash line which is the outline of the porous material...but there is extra space beyond that between – which is an empty space...”).) There is no “chamber of void space positioned” in this location. The unrebutted testimony is that area that is supposed to be “void space” is filled with batting as shown in DTX680 and JTX15. (Tr. 822-824; SDX6.56.) Moreover, vacuum causes the plastic film layers to pull into the other layers eliminating any air pockets whatsoever. (Tr. 824.) Thus, there is no “chamber of void space positioned” between the two layers,⁸ much less one “configured to collect urine for transport.”



Moreover, when asked whether the “chamber [has] a port for receiving a tube,” Collins responded that the “impermeable material basically forms a port which seals the tube.” (Tr. 490-491.) But Claim 1 requires the chamber, formed by the porous layer and impermeable layer, to include the



port—not two layers of impermeable material. (JTX4.) Collins’ own image shows that the port (purple labelling added) is separated well away from the white porous material and not within it. (JTX15; PDX4.68; Tr. 824-825.) Sheldon explained why those elements were not present. (Tr. 822-825; SDX6.56.) Accordingly, no reasonable jury could have found that PureWick satisfied its burden of proving PrimoFit infringes. JMOL or a new trial is warranted.

III. JMOL AND A NEW TRIAL ON INVALIDITY IS WARRANTED

The jury could not reasonably conclude that Sage failed to prove invalidity. Most of Sage’s evidence was completely unrebutted and undisputed. Because the jury’s findings were unduly influenced by legally irrelevant and prejudicial arguments, the jury did not give appropriate

⁸ Moreover, there is no “chamber positioned” between the layers because the prosecution history establishes that there can be no material between them. (DTX51 at 357-358, 364, 394; D.I. 105 at 69-74; D.I. 128 at 2, 11-13; Tr. 822-824.) Claim construction issues are reserved for appeal.

consideration to the weight of the evidence. JMOL or a new trial are warranted.

A. PureWick’s Prejudicial And Legally Incorrect Arguments About The State Of The Art Warrant A New Trial

PureWick made a number of legally irrelevant and factually false arguments that misled the jury regarding the relevant state of the art at the time of the invention. Over Sage’s objections, PureWick argued that the prior art did not result in commercially-available products (PDX8.78-.80, Tr. 633, 709-710, 832-844, 1175-1176 (“Does anybody here...think that there was any commercially viable product?”).) Aside from being untrue (DTX523A, 525A, Tr. 704-705, 743), the argument was meant to leave the jury with the misimpression that to invalidate a patent, prior art must have resulted in a commercial product. That is not the law. 35 U.S.C. §102; *Pfaff v. Wells Elecs*, 525 U.S. 55, 66 n.12 (1998) (“an invention did not need to be subsequently commercialized to constitute prior art”); *Trs. of Columbia Univ. v. Illumina*, 620 F. App’x 916, 932 (Fed. Cir. 2015). Sage requested a clarifying jury instruction so the jury was not misled into believing a commercial product was necessary, but the Court erroneously denied it. (Tr. 1039-40.)⁹

Another error occurred in PureWick’s repeated theme of its “invention story” involving Robert Sanchez. (PDX1.19-1.26; PDX8.2-8.9.) Over Sage’s objections, PureWick told a story of invention in 2009-2010 by Sanchez, repeatedly displayed images of the device made for his wife, and inappropriately implied that the 376 and 989 patents embodied this 2009/2010 invention, even though that invention related to the invalidated 508 patent filed in 2010. (PDX8.17-26; PDX1.34-1.46; Tr. 10-12, 98-99, 101-104, 1179; *compare* PDX-1.19, 1.22 with JTX1, Figs. 1-3.) Sage raised

⁹ PureWick suggested that lack of commercialization is somehow relevant to “failure of others.” But a patent application is not a “failure” but a constructive reduction to practice. *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 975 (Fed. Cir. 2014). In any case, a “failure” must be failed attempts to make the claimed invention—not failure to commercialize. *UCB v. Watson Labs.*, No. 14-1083-LPS-SRF, 2017 WL 11646645, at *35 (D. Del. Nov. 22, 2017) (“That the Cygnus patches were not developed commercially...does not establish failure of others”).

the concern that PureWick would tell a story of Sanchez's "valuable" "innovation" and imply that it related to the 376 and 989 patents. (D.I. 286-18; DTX818; D.I. 286-21, D.I. 296, Tr. 3/21/22 Tr. 10-17.) PureWick did just that even though there was no evidence that Sanchez had any role in the invention of the purportedly novel aspect of the 376/989 patents. (Tr. 320, 282.) Due to the prior rulings, Sage was not permitted to counter PureWick's narrative by presenting evidence that Sanchez's 2009 invention was not inventive (Tr. 16, 91-92, 506-510, 746-747; Section C *infra*.)

As a result of these errors and others discussed herein, the jury was left with a misimpression of Sage and a misunderstanding of the alleged "invention" of the 376 and 989 patents as well as the prior art. These prejudicial rulings warrant a new trial on invalidity. *See, e.g., GN Netcom v. Plantronics*, 930 F.3d 76, 88-89 (3d Cir. 2019).

B. PureWick Provided No Witness Testimony or Evidence Rebutting Anticipation Or Obviousness of the 376/989 Patents By Van Den Heuvel

JMOL of invalidity of the 376 and 989 patents should also be granted on the merits. Sage's expert (Sheldon) explained in detail how Van Den Heuvel 823 (DTX12) anticipates or renders obvious every asserted claim of the 376 and 989 patents. (Tr. 776-787, 793-812.) Sheldon explained how the elements were disclosed by Van Den Heuvel including the only two disputed elements (reservoir and permeable membrane). (Tr. 780-788, 793-812; SDX6.16-43.) PureWick's invalidity expert never discussed Van Den Heuvel, much less disagreed with Sheldon's opinions. (Tr. 938-952; D.I. 312 at 1-2.) For example, Sheldon explained how Van Den Heuvel discloses a "fluid reservoir (Tr. 782-783), and PureWick's expert never provided any contrary opinion nor was Mr. Sheldon asked about it during cross. (Tr. 938-952, 829-871.) Similarly, Sheldon explained that Van Den Heuvel discloses a "fluid permeable membrane disposed on the support"—both directly and through incorporation by reference. (Tr. 784-787, 793-797; DTX12; DTX13.) PureWick's expert again did not dispute that opinion nor was Sheldon questioned about it other

than asking whether he annotated a figure. (Tr. 938-952, 829-871.) PureWick likewise did not challenge that the dependent claims were anticipated or obvious, i.e., namely because substantially cylindrical designs were well known in the art. (Tr. 801-812; JTX1 at claims 5, 9; DTX21.)

Absent any evidence that Van Den Heuvel was missing an element, the jury was left to rely on PureWick's other, legally irrelevant points about whether Van Den Heuvel made a commercial product (Tr. 832-844, 1175-1176; *see* Section A) or whether an exhibit ("Van Den Heuvel 894") that was never entered as evidence was considered by the PTO (Tr. 849-858, 845-858, *see infra*). In any case, whether Van Den Heuvel 823 was considered during the prosecution does not mean it cannot invalidate. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 966 (Fed. Cir. 2014).

The Court should grant JMOL or grant a new trial on this issue.

C. The Jury's Finding of No Obviousness Of The 407 Patent Is Not Supported by Substantial Evidence And Prejudicial Statements Misled The Jury

"Obviousness is a question of law based on underlying findings of fact." *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019). The evidence at trial regarding obviousness of the 407 patent was likewise one-sided. Dr. Newman explained how Suzuki (DTX8) rendered obvious both of the asserted Claims 1 and 2 of the 407 patent. (Tr. 702, 714-726.) There was no question that Suzuki disclosed all of the elements with one exception. (Tr. 943-946.) The only disputed issue was whether it would have been obvious to replace Suzuki's top layer with a wicking material, which Newman explained was a well-understood design option. (Tr. 702, 714-726.) Jezzi's entire rebuttal focused on whether the top layer was a wicking material rather than whether it would be obvious. (Tr. 943-944) With respect to whether it would have been obvious to use a wicking material as a patient-facing layer, Jezzi admitted that it was a known design option and never disputed why it would have been beneficial. (Tr. 955-956.) This is the epitome of obviousness. *Uber Techs., Inc. v. X One*, 957 F.3d 1334 (Fed. Cir. 2020). Jezzi opined that Suzuki

purportedly preferred a non-wicking material but preference to use a certain material is not relevant to known design choices or evidence of teaching away. *DePuy Spine v. Medtronic Sofamor Danek*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). The jury's verdict of non-obviousness cannot stand. *See W. Union Co. v. MoneyGram Payment Sys.*, 626 F.3d 1361, 1372 (Fed. Cir. 2010).

Regarding adding a lip (claim 2), Newman explained why this was an obvious design choice to prevent urine splash back and identifies references showing a lip (Harvie, Ishii, and Hanifl). (Tr. 724-726; DTX16, Figs. 4-5; DTX17, Figs. 1, 3; DTX29; Tr. 708, 743.) Jezzi did not address Harvie, Ishii, or Hanifl; his testimony consisted solely of his opinion that “there is no mention of a lip” in Suzuki and using a lip is “not a design option that is commonly practiced.” (Tr. 945-946.) But the point of obviousness is that, while Suzuki does not disclose a lip, adding one would have been obvious. *Trebro Mfg. v. FireFly Equip*, 748 F.3d 1159, 1169 (Fed. Cir. 2014).

Rather than address obviousness, PureWick reprised its legally irrelevant arguments that Suzuki was a “failure” because it had purportedly not resulted in a commercial product and that Suzuki was before the PTO, again leaving the jury with the misimpression that prior art can only invalidate a patent if it was not previously considered. (Tr. 1168, 738-742, 1181-1182; PDX8.78; *see* Section A.) Further, during cross, PureWick elicited the misleading testimony that Newman had never invalidated a patent, implying that her testimony could not supplant that of the PTO. (Tr. 742 (“Q. Now,...you had never offered opinions as an expert witness on the issue of patent validity...”)) The truth was—though the jury was precluded from hearing it—that Newman had performed an invalidity analysis, the PTO accepted it, and PureWick’s patent was invalidated. (Tr. 746; DTX818.) With the inaccurate record that it had established, PureWick argued that “So when you’re weighing on clear and convincing evidence between Dr. Newman who has never done a validity analysis and the Patent Office ... I think it’s hard to come to the conclusion that they met

their burden.....” (PDX-8.111; Tr. 1181-82.) JMOL and/or grant a new trial should be granted.

IV. JMOL AND A NEW TRIAL ON WILLFULNESS SHOULD BE GRANTED

The jury found willful infringement of the 376 and 989 patents even though PureWick never presented any evidence of post-issuance willful activity. PureWick submitted no evidence in its case-in-chief that Sage had knowledge of the 376/989 patents (much less at any particular time) or that Sage undertook any wrongful or willful act after issuance in March/August 2019. Instead of proving willful infringement after patent issuance, PureWick argued that Sage knew about a three-year old patent application and “copied” a “PureWick product” three years earlier—without ever presenting any evidence of Sage’s product development in its case-in-chief, without identifying any particular product that Sage purportedly copied, and without providing any evidence that any “copied” product was covered by the patents. (*See, e.g.*, Tr. 108-112, 1150-1156, 216-217, PDX8.29-45.) This is not sufficient to establish willfulness. Moreover, PureWick improperly tried to prove copying by comparing Sage’s product to patent figures. These prejudicial errors permeated the trial and misled the jury, warranting a new trial on all issues. No reasonable juror could have found willfulness, much less based on the evidence in PureWick’s case-in-chief.

A. PureWick Offered No Evidence of Any Post-Issuance Willfulness

PrimaFit launched in 2017 (Tr. 605) but the 376 and 989 patents did not issue until March and August 2019. (JTX2; JTX3). PureWick cannot establish willfulness as a matter of law because there is no evidence in the record that Sage acted willfully after having knowledge of the patents.

First, “knowledge of the asserted patent...is necessary... for a finding of willfulness.” *Bayer Healthcare v. Baxalta*, 989 F.3d 964, 988 (Fed. Cir. 2021). Yet, in its case-in-chief, PureWick submitted no evidence that Sage knew of the 376/989 patents at all, much less at any particular time after issuance. This alone is fatal to PureWick’s willfulness claim. *Id.* Indeed, in contravention of law, PureWick’s counsel argued that he “d[id]n’t know what the relevance of the

patent issuing is as to their knowledge of the patents.” (Tr. 12.)

Moreover, PureWick presented no evidence that Sage had knowledge of infringement or intent to infringe after the patents issued in 2019. But “[w]illful infringement is not established by the simple fact of infringement....The patentee must present threshold evidence of culpable behavior....[including whether the accused] acted reasonably once it acquired knowledge of the patent.” *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1332 (Fed. Cir. 2004) (affirming grant of JMOL of no willfulness after case-in-chief). Simply put, “knowledge of the asserted patent and evidence of infringement is necessary, but not sufficient, for a finding of willfulness. Rather, willfulness requires deliberate or intentional infringement.” *Bayer*, 989 F.3d at 988. Timing of knowledge is important because, “[t]o establish willfulness, the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct.” *Id.* at 987. Yet, PureWick introduced no evidence regarding Sage’s state of mind or intent. (Tr. 216-217, 611-628, PDX8.26-45.) Indeed, PureWick presented no evidence of a single post-issuance act by Sage whatsoever. But infringement alone is not enough to establish willfulness; knowledge of infringement must be proven and cannot be assumed. *Bayer*, 989 F.3d at 988 (granting JMOL of no willfulness where trial evidence “merely demonstrates Baxalta’s knowledge of the ‘520 patent and...direct infringement” but “willfulness requires deliberate or intentional infringement”); *Acceleron v. Dell*, No. 1:12-cv-4123, 2022 WL1087683, at *5 (N.D. Ga. Mar. 7, 2022); *Optolum, Inc. v. Cree, Inc.*, No. 1:17CV687, 2021 WL5505794, at *3 (M.D.N.C. Nov. 24, 2021).

B. Years-Old “Pre-Issuance” Activity Could Not Establish Willfulness

The evidence that PureWick did present to the jury is legally insufficient to establish willfulness and was improperly prejudicial to Sage. PureWick’s willfulness case hinged on two pre-issuance acts, both of which occurred in 2016, three years before either patent issued: (1) Sage’s purported knowledge of a 2016 patent application and alleged copying of a figure from that

application; and (2) alleged “copying” of an unidentified “PureWick product” even though PureWick provided no evidence that Sage ever received any patented PureWick product.¹⁰ (*See, e.g.,* Tr. 108-112, 1150-1156, 216-217.) Neither can establish willful infringement. “‘A party cannot be held liable for ‘infringement,’ and thus not for ‘willful’ infringement, of a *nonexistent patent*.’” *bioMerieux, S.A. v. Hologic, Inc.*, No. 18-21-LPS, 2020 WL 759546, at *12 (D. Del. Feb. 7, 2020). That is because “[t]o willfully infringe a patent, *the patent must exist* and one must have knowledge of it.” *State Indus. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985). These principals are dispositive here because PureWick’s willfulness case rests solely on conduct that undisputedly occurred long before the patents issued.

1. Knowledge Of An Old Patent Application Is Not Willfulness

“***Knowledge of a patent application*** alone...is not enough to establish knowledge of the patent(s) that issued from that application and therefore ***not enough to establish willfulness***.” *iFIT Inc. v. Peloton Interactive, Inc.*, No. 21-507-RGA, 2022 WL609605, at *2 (D. Del. Jan. 28, 2022). That is because the mere “[f]iling [of] an application is no guarantee any patent will issue and a very substantial percentage of applications never result in patents” and “[w]hat the scope of claims in patents that do issue will be is something totally unforeseeable.” *State Indus.*, 751 F.2d at 1236. Indeed, courts decline to find willfulness based on knowledge of patent applications. *See, e.g., Conopco, Inc. v. May Dep’t Stores Co.*, 46 F.3d 1556, 1562 (Fed. Cir. 1994) (“Although these activities may have been undertaken with knowledge that a patent application...was pending ... that is insufficient to support a finding of willfulness.”); *iFIT*, 2022 WL609605, at *2; *bioMerieux*, 2020 WL 759546, at *12. And, here, the “knowledge” of a patent application is even less relevant

¹⁰ At trial, PureWick acknowledged that it had failed to prove that Sage had copied a patented PureWick product. (Tr. 1028, 660, 664-65; *see supra*.) Thus, PureWick’s only articulated basis for willfulness was that Sage had received the 2016 application. (Tr. 216-217; PDX1.39, PDX8.20.)

because (1) Sage purportedly received it years before the patents issued and years before the claims as issued were written (PTX158; JTX5A.3-7; JTX6A.2-3); (2) PTX158 does not include the same disclosure as the 376 patent, which is a CIP (*compare* PTX158 and JTX2); and (3) the PrimaFit designer never saw any PureWick patent or patent application, much less a figure (Tr. 610).

Moreover, PureWick’s repeated assertion that Sage “copied” a patent application figure (Tr. 108-116, 435-474, 504, 1150, 1155; PDX1.39-1.47, PDX8.20) is highly prejudicial and legally irrelevant. As discussed in Section II.A.5, “infringement is to be determined by comparing the asserted claim to the accused device, not by comparing the accused device to the figures of the asserted patent.” *Catalina*, 295 F.3d at 1286; *Star Tech.*, 1999 WL 693829, at *6 (“figures of the patent specification” cannot be infringed); D.I. 286-20 at 2.) Thus, alleged copying of a *figure* in an application is irrelevant to showing knowing infringement of later-issued patent *claims*. *Bioverativ Inc. v. CSL Behring LLC*, 17-914-RGA, 2020 WL 1332921, at *2 (D. Del. Mar. 23, 2020). The Court erred in allowing the evidence. (Tr. 115-116, 537-539). In any case, there was no evidence that PrimaFit includes any patented features from the patent figure. PureWick only alleged that the two look similar (PDX1.16-18; PDX8.20; Tr. 108-116, 435-439, 539-540, 1150, 1155), but superficial look-a-like comparisons do not establish copying. *Sonos v. D&M Holdings*, No. CV 14-1330-WCB, 2017 WL 5633204, at *3 (D. Del. Nov. 21, 2017). That is particularly true since Sage received a patent on the design (though the Court precluded that evidence). (DTX701; D.I. 296 at 4-5). PureWick’s old application is irrelevant, and JMOL or new trial should be granted.

2. PureWick’s Years-Old Copying Theories Did Not Establish That Sage Copied Any Product, Much Less A Patented One

PureWick’s second alleged pre-issuance act—Sage’s “copying” of an unidentified “PureWick product” three years before the patents issued—is also legally irrelevant, contrary to the evidence, and prejudicial. As a preliminary matter, “[e]vidence that the defendant copied the

plaintiff's products prior to the issuance of the plaintiff's patent is inadmissible, either because pre-issuance conduct is not relevant to willfulness or because of the risk that the jury will improperly use the evidence of pre-issuance copying to conclude that the defendant's product infringes the plaintiff's patent.” *Sonos*, 2017 WL 5633204 at *3 citing *MasterObjects, Inc. v. Google, Inc.*, No. C 11-1054, 2013 WL 12177460, at *1 (N.D. Cal. May 2, 2013) (pre-issuance conduct not relevant to willfulness); *Interlace Med. v. Hologic*, No. 10-10951, 2012 WL 3560811, at *2 (D. Mass. Aug. 17, 2012) (“Conduct before the patent issues is not willfulness”); *State Indus.*, 751 F.2d 1226, 1236 (rejecting evidence of pre-issuance activity); Tr. 10-12, 1013-1015.

Indeed, in *Bioverativ*, 2020 WL 1332921, at *5, the court granted summary judgment of no willfulness despite preissuance “copying” allegations because the alleged copying was ordinary “competitive intelligence.” The court held that “[c]opying a product which is not protected by the patent laws is not illegal and does not constitute infringement” and “there can be no willful infringement before a patent is issued.” *Id.* at *3,*4. Yet, here, despite this established law, PureWick vilified ordinary engineering activity that did not legally amount to willful activity.¹¹

Moreover, “*evidence of copying...is legally irrelevant unless the [product] is shown to be an embodiment of the claims.*” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1366 (Fed. Cir. 2001). Yet, PureWick presented no evidence that Sage had access to any patented PureWick product. PureWick’s only evidence was that it sent unidentified PureWick products to Sage, but PureWick presented no evidence—much less substantial evidence—of what those

¹¹ Sage’s development activities were exactly the sort of routine “competitive intelligence” that *Bioverativ* found irrelevant to willfulness. *See id.* at *5. (Tr. 607-608, 812-813; DTX149, DTX141; Tr. 375-378.) Sage did not copy but made a better product (Tr. 583-586, 597-598, 605-610, 615, 633; DTX903; DTX187; JTX14E; DTX165; DTX772), and the Court precluded Sage from presenting evidence it received multiple patents on its innovations. (D.I. 296 at 4-5; DTX700; DTX701.) Sage reserves its rights regarding those *in limine* rulings.

products were or that any were patented. To the contrary, PureWick’s witnesses testified that it had “hundreds and hundreds” of versions (Tr. 173, 291, 297) and PureWick’s witnesses did not know what products were provided. ((Tr. 224, 257-58) (“Q. So you have no personal knowledge of what version wick was sold to Sage...; correct? A. Correct.”; “Q. So you’re not sure what the timing was on any particular version of any wicks that were sold or provided to Sage; correct? A. That is correct.”).) The PrimaFit designer likewise did not know. (Tr. 608.) PureWick presented no evidence—much less substantial evidence—of what products were “copied” or that any were patented. (Tr. 267, 323.) Indeed, to avoid invalidity, PureWick disputed that its “hundreds and hundreds” of products were patented (Tr. at 74, 78, 82-83), and PureWick’s counsel repeatedly conceded that PureWick would only argue willfulness based on the 2016 patent application. (Tr. 660, 664-65, 1028 (“as my colleagues said the other day, he wouldn’t be arguing that [Sage copied a covered product], we argue that...the patent application in advance [they] copied those”).¹²

Importantly, PureWick presented no evidence of copying in its case-in-chief. There was no evidence that the PrimaFit engineer had access to any PureWick product; indeed, there was no testimony in PureWick’s case regarding PrimaFit product development whatsoever. There was no evidence that Sage copied a patented feature even though that is required. *Sonos*, 2017 WL 5633204, at *3. Sage moved for JMOL on this failure of proof and objected to PureWick’s attempts to argue “copying” of an unidentified, unpatented “PureWick product.” (Tr. 12, 653-666, 928-939, 984, 992.) JMOL should have been granted at the close of PureWick’s case rather than allowing inappropriate copying allegations to propagate through the trial. *Norian*, 363 F.3d at 1332; *Amgen*

¹² While PureWick alleged “copying” without establishing that any particular product had been copied, Sage was prohibited from offering evidence on any PureWick products subject to the on-sale/public use bar without proving “what pictures of what product...You’re going to say we are going to prove that the brown tape product in this picture” is prior art. (D.I. 296 at 90-91.) Sage reserves its rights on the rulings that impeded its ability to present its prior art defenses at trial.

v. Sanofi, No. 14-1317-RGA, 2019 WL 4058927, at *6 (D. Del. Aug. 28, 2019).

Unthwarted, PureWick argued that Sage had copied “an original version which was made of components and tape” (Tr. 1152) even though it previously conceded no witness had testified that Sage received *any* patented product (much less a “taped” one). Sage sought a clarifying jury instruction but that request was wrongly denied.¹³ (Tr. 1013-15.) But even if such preissuance activity were relevant, PureWick never connected it to any post-issuance act by Sage. *See* Section IV.A. “[K]nowing infringement” cannot be based on pre-issuance acts because there were no patents, and PureWick bore the burden of proving that Sage knew it was infringing after there were issued claims. No reasonable jury could have found willful infringement. The Court should either grant JMOL on willfulness (particularly after the close of PureWick’s case-in-chief) or a new trial.

C. A New Trial On Willfulness Is Warranted Based On Improper, Unsupported, And Misleading Arguments Made By PureWick At Trial

As explained above, PureWick’s inappropriate copying allegations permeated the entire trial on every issue, prejudicing the jury. This alone warrants a new trial on all issues. Moreover, as discussed in Section II.A.5, in contravention of law, PureWick was permitted to compare PrimaFit with patent figures and PureWick’s products (including unpatented products). PureWick drew these comparisons to suggest infringement and copying, which the Court permitted. (Tr. 115-116; D.I. 286-20 at 1-2; D.I. 296 at 18-19.) Such comparisons were improper for infringement or copying. *Catalina*, 295 F.3d at 1286; *Amazon.com*, 239 F.3d at 1366. Further prejudicing the jury, PureWick argued that copying was “proven” because, according to PureWick’s counsel, certain Sage prototypes correlated to notebook entries regarding PureWick even though no evidence

¹³ In *Nox Med. Ehf v. Natus Neur.*, No. 15-709-RGA, 2018 WL6629704, at *2 (D. Del. Apr. 12, 2018), the court allowed copying evidence but instructed the jury that “it is perfectly lawful to copy unpatented products” so that “the jury does not find the Defendant acted willfully for non-infringing and lawful conduct.” Sage requested this instruction and the Court erred in denying it.

substantiated those correlations. (PDX8.24, 8.29-8.38, 8.40-8.42; Tr. 1091-92, 1152-1154.) These arguments, with no evidentiary predicates, were prejudicial and warrant a new trial.

V. JMOL AND A NEW TRIAL, OR A REMITTITUR, ON DAMAGES SHOULD BE GRANTED

“[T]he availability of lost profits is a question of law for the court, not the jury.” *Wechsler v. Macke Int'l Trade*, 486 F.3d 1286, 1293 (Fed. Cir. 2007). To prove lost profits, PureWick had the burden to establish (1) demand for the patented product, (2) an absence of acceptable noninfringing alternatives (“NIAs”), (3) manufacturing and marketing capability, and (4) the amount of profit. *Rite-Hite v. Kelley*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). Here, PureWick never presented lost profits based on a market share analysis, but rather contended that there was a two-supplier market with no NIAs. Substantial evidence does not support the jury award. JMOL of no lost profits is appropriate and a new trial including to identify a royalty or a remittitur is necessary. *Presidio Comp. v. Am. Tech. Ceramics*, 875 F.3d 1369, 1381-82 (Fed. Cir. 2017).

A. Despite Its Burden, PureWick Never Rebutted Evidence of Sage’s Acceptable, Noninfringing Design Alternative

Despite being required to prove the absence of NIAs, PureWick never refuted non-infringing PrimaFit design modifications and thus no reasonable jury could have found that there were no NIAs. A “fair and accurate reconstruction of the ‘but for’ market also must take into account...actions the infringer foreseeably would have undertaken had he not infringed.” *Grain Processing v. Am. Maize*, 185 F.3d 1341, 1351 (Fed. Cir. 1999). “[A]n alleged substitute not ‘on the market’ or ‘for sale’ during the infringement can figure prominently in determining whether a patentee would have made...profits ‘but for’ the infringement.” *Id.* at 1349.

Sage presented evidence of a simple PrimaFit design alternative that was acceptable, available, and non-infringing (*i.e.*, shortening the absorbent fabric on the PrimaFit). (SDX6.59-60; DTX532A at 8.) The PrimaFit lead engineer and Sage’s technical expert testified to the design,

availability, and acceptability of this proposed NIA. (Tr. 606-607, 827-829). Sage's damages expert (Thomas) testified that, in light of the alternative, Sage would not simply exit the market if faced with patent infringement. (Tr. 895, 900.) Despite its burden, PureWick presented no testimony from any of its witnesses that the alternative was unacceptable, unavailable, or infringing, and none of Sage's witnesses were cross-examined on it. (Tr. 611-633, 829-871, 914-924). No evidence countered Sage's NIA and thus no reasonable jury could find lost profits as a matter of law. *Presidio*, 875 F.3d at 1381 (reversing denial of JMOL and setting aside lost profits award where patentee "failed to provide evidence that [defendant's NIA] was either not acceptable or available substitute" and finding that "a new trial is needed to determine the reasonable royalty award"); *Grain*, 185 F.3d at 1351. JMOL and a new trial to determine a royalty rate is warranted.

B. The Testimony of PureWick's Expert Demonstrates the Existence of Acceptable NIAs and Inability to Prove Marketing Capability

Numerous other alternatives were on the market including "diapers, catheters, external or portable urinals, bedpans, other toileting devices, incontinence pads" including Sage's Microclimate body pad. (Tr. 673-681; DTX165; DTX525A; DTX523/A; PTX42; PTX229 at 9; PTX486; SDX5.6, 38-39; Tr. 369-370, 379-380; 573-574, 582, 727-730, 894-900, 912.) PureWick's damages expert acknowledged the existence of NIAs and the inability of PureWick to demonstrate sufficient marketing capability by excluding two customers from his analysis. (Tr. 564-574.) The record included numerous examples of customers that did not want Bard's products because of quality issues. (Tr. 371-375, 676-681, 896-897; DTX89; PTX180 at 10, DTX142.) That certain customers in the "but for" world would not use PureWick necessarily means they are using an NIA for urine management. (Tr. 369-375, 673-681, 573-574). Similarly, PureWick's inability to sell due to a "grudge" or product failures shows insufficient marketing capability. (Tr. at 564.)

PureWick's witness (Gohde) testified that not all hospitals used PureWick or PrimaFit and

PureWick's documents reflect less than 100% market share for those products. (Tr. 369-370, 375, 379-380; PTX229 at 9.) The evidence showed "many hospitals...have not chosen to use PrimaFit and PrimoFit, PureWick, and continue to use those other products that are available." (Tr. 673, 680-681, 375.) Dr. Newman testified to the numerous alternatives on the market, having authored a book on the topic.¹⁴ (Tr. 727-30; DTX525A.) Despite the evidence and PureWick's problems, PureWick did not present evidence from any PrimaFit user and failed to show anyone (much less everyone) would use PureWick if PrimaFit were unavailable. (Tr. 421-422, 730-32.)

C. There Was No Apportionment And The Trial Evidence Did Not Establish Demand for the Patented Product

PureWick also did not prove demand for its product or apportion for the patented features. PureWick "would not have made some or all of the diverted sales 'but for' the infringement." *Micro Chem. v. Lextron*, 318 F.3d 1119, 1125 (Fed. Cir. 2003). As discussed, there were quality issues with PureWick's product and Gohde admitted that he did not know "whether or not the reason why hospitals buy the PureWick has anything to do with the patents in this lawsuit." (Tr. 370; DTX403-404; DTX142; DTX196.) He conceded that "there is a variety of factors" such as timing, price, and sales force effectiveness that drove sales and admitted "at least some hospitals wouldn't use PureWick regardless of any competition from Sage." (Tr. 370-75.) Leonard also recognized that non-patented features, such as being latex free, drove sales. (Tr. 576-57, 896-899, 364-375.) Substantial evidence at trial showed what drove demand for PrimaFit was non-patented features that made PrimaFit superior in fit, securement, and performance. (Tr. 599-601, 669-683, 730-732, 895-901; DTX165, DTX193, DTX772, DTX755; PTX42, PTX486.) Indeed, there was no evidence that demand was driven by a patented feature as opposed to other factors or the

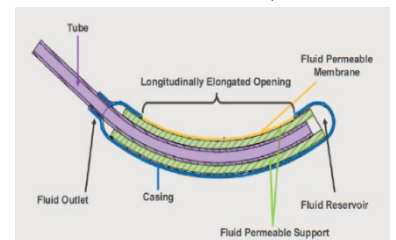
¹⁴ The jury believed that there were NIAs, making notations relating to "85%" next to the lost profits award. (D.I. 316 at 5 ("15% on nonusing facilities").) But no evidence supports the "15%."

prior art (e.g., alleged inventions of the 508 patent). And PureWick's lost profits claim was never apportioned to account for the value of the 376/989 inventions even though "[a]pportionment is required even for non-royalty forms of damages." *Ericsson v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014). Indeed, PureWick sought the same amount in damages after the 376/989 patent issuance dates with or without the invalidated 508 patent. (D.I. 211, Ex.38) Thus, JMOL and new trial should be granted or, alternatively, a remittitur on damages.

VI. JMOL THAT PUREWICK'S "BLUE SILICONE SHELL" PRODUCT IS NOT COVERED BY ITS PATENTS SHOULD BE GRANTED

PureWick repeatedly tried to imply that its products were successful without ever specifying which of the "hundreds and hundreds" were responsible. (Tr. 105-10, 1147-1148.)

PureWick attempted to establish that its latest "blue silicone shell" version was covered by the 376/989 patents. (Tr. 161, 440-444.) But the product does not include "a tube having a first end disposed in the reservoir." As



can be seen in this annotated image from Collins, the tube (purple) is not disposed in the reservoir, but terminates well short of it. (PTX421; PDX4.3, 4.15; JTX13; Tr. 504-505.) Additionally, Collins never addressed the limitation "fluid impermeable layer coupled to the fluid reservoir." (Tr. 440-444, 657-658.) The Court should grant JMOL on this issue and a new trial on the issues of willful infringement, invalidity, and damages should be granted.

VII. CONDITIONAL MOTION TO AMEND THE JUDGMENT

Sage does not believe that the judgment should be amended to include claims and defenses withdrawn for case narrowing purposes. But if PureWick seeks such an amendment (D.I. 321, 2), the judgment should be amended to include a finding of noninfringement on claims not asserted at trial (376 Patent, claims 2-4, 6-8, 10-14; 989 Patent, claims 2-5; 407 Patent, claims 3-16).

Dated: May 5, 2022

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